

## REMARKS

Claims 1-41 are currently before the examiner. Claims 7-12, 16-18, 28-33 and 37-39 have been withdrawn by the examiner as, in the examiner's opinion, relating to a separate and distinct invention. Claims 1, 19 and 40 have been amended to more accurately reflect that which the inventor considers the invention. The amendment, which comprises adding the chemical name, O,O'-bis-2-aminopropyl-(poly(propylene glycol)-b-poly(ethylene glycol)-b-poly(propylene glycol), and its acronym, ED<sub>600</sub> as used in chemical formulae herein, is fully supported by the specification. See, e.g., Example 4, Example 19 and Example 21.

### **37 CFR §1.75(c) claim objections**

The examiner has objected to claims 20 and 41 under § 1.75(c) as being in improper dependent form in that they include an element ED<sub>600</sub> which is not presented in the claim from which claim 20 and 41 depend, i.e., claims 19 and 40.

The examiner also objects to "a stray parenthesis" in Claim 28.

### **Applicant's response**

Applicant has amended claims 19 and 21 to include ED<sub>600</sub> as a member of a Markush group such that its election from that group as an element of a copolymer of claims 20 and 41 is proper and does further limit the parent claim.

The errant parenthesis has been repositioned in Compound 28 wherever it appears.

The examiner is requested to withdraw the rejections.

### **35 U.S.C. § 103 rejection of claims 1, 3-6, 13-15, 19-21, 23-27, 34-36, 40 and 41**

The examiner has rejected claims 1-6, 13-15, 19-24, 26, 27, 34, 40, and 41 as being unpatentable over Katsarava, et al., U.S. Pub. Pat. App. No. 2002/0015720 in view of Katsarava, et al., Journal of Polymer Science: Part A, 1999, 37:391-407 (Katsarava B) and Nagata, Polymer International, 1997, 42:33-38.

In the examiner's view, Katsarava and Katsarava B, which disclose DACA (D = diol, A =  $\alpha$ -amino acid, C =  $\alpha,\omega$ -diacid) and CADA polyester amides, together with Nagata, which teaches the use of poly(ethylene glycol) in polyesters renders applicant's CADA-CADA copolymers obvious to one skilled in the art. The examiner's argument is that it would have been obvious to one skilled in the art to prepare a medical article with

a copolymer of a CADA poly(ester amide) of Katsarava and Katsarava B, where the coating polymer was the block copolymer of two CADA monomers resulting from coupling of an 8-L-Leu-6 block to a similar block where PEG is exchanged for the hexanediol.

Applicant traverses.

### **Applicant's response**

To render a claim obvious under U.S. patent law it is necessary to provide some rational basis upon which one of ordinary skill in the art would consider taking the step(s) necessary to achieve the claimed subject matter beginning from the prior art. KSR International Co. v. Teleflex, Inc. et al., 127 S.Ct. 1727 (2007).

The differences between the art cited by the examiner and the present invention are huge. Nowhere in Katsarava, Katsarava B or Nagata are copolymers disclosed. Applicant's polymers are all copolymers. Nagata teaches only polyesters while the current invention is directed solely to poly(ester amide)s, a entirely different class of compounds. Nevertheless, the examiner blithely assumes that one of ordinary skill in the art would somehow come to the conclusion based on Katsarava and Katsarava B that it would be nice to make CADA-CADA copolymers. That, however, is not all. The skilled artisan would then have had to decide, based on Nagata's work with an entirely different type of polymer, to substitute Nagata's poly(ethylene glycol) for one and only one of the hexanediol elements of the CADA-CADA copolymer. The examiner tries to rationalize these gigantic leaps of reason by propounding at length how it would have been known at the time how to prepare such compounds.

In the first place the mere fact that the chemistry might have existed to put applicant's compounds together is irrelevant. If the compound is new, it's patentable and applicant's compounds are new.

Further, there is absolutely nothing to lead the person of average skill in the art to consider making the copolymer. Katsarava and Katsarava B are by their very explicit language limited to CADA and DACA polymers and offer not the slightest suggestion that would lead the skilled artisan upon reading those references to so much as give pause to consider applicant's copolymer.

In short, the only way one could come to the present invention by way of Katsarava, Katsarava B and Nagata is through an as egregious a hindsight analysis as could possibly be imagined. Without applicant's novel and structurally complicated compounds as a template, there is absolutely no way the skilled artisan would for any rational reason be drawn to so much as consider applicant's compounds.

The examiner is requested to reconsider and based thereon withdraw the rejection.

### **35 U.S.C. § 103 rejection of claims 1, 2, 21 and 22**

The examiner has rejected claims 1, 2, 21 and 22 under § 103(a) as being unpatentable over Katsarava, Katsarava B in view of Nagata and, further, Michal, U.S. Pub. Pat. App. No. 2002/01120326.

In the examiner's view, Katsarava, Katsarava B and Nagata render obvious a coated medical article and its claimed method of production where the polymer coating includes applicant's poly(ester amide)s. The examiner, however, admits that none of the preceding references explicitly teach that the article is a stent but Michal does.

Applicant traverses.

### **Applicant's response**

As explicated at length above, Katsarava, Katsarava B and Nagata do not even come close to rendering the coated medical article and its claimed method of production where the polymer coating includes applicant's novel copolymeric poly(ester amide)s. All that Michal teaches that might have even the slightest relevance to the present invention is, as the examiner notes, that poly(ester amide)s can be used on stents. Like Katsarava, Katsarava B and Nagata, however, Michal makes no mention of copolymeric poly(ester amide)s and therefore cannot even arguably supply any of the fatally missing elements in Katsarava, Katsarava B and Nagata to so much as approach applicant's invention, much less render it obvious. The combination of Katsarava, Katsarava B, Nagata and Michal cannot and does not render claims 1, 2, 21 and/or 22 obvious.

The examiner is requested to reconsider and based thereon withdraw the rejection.

### **CONCLUSION**


Based on the above remarks, applicant believes that this application is in condition for allowance and respectfully requests that it be passed to issue.

Applicant does not believe any fee is due with this response. If this is incorrect, the examiner is authorized to charge any amount due to Squire, Sanders & Dempsey Deposit Account No. 07-1850.

Date: 30 June 2009

Squire, Sanders & Dempsey L.L.P.  
One Maritime Plaza, Suite 300  
San Francisco, CA 94111-3492  
(415) 954-0200

Respectfully submitted,



Bernard F. Rose  
Reg. No. 42,112